ATTACHMENT B

FDA News Release

FDA takes additional action to better understand safety of Essure, inform patients of potential risks

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Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm488375.htm)

The U.S. Food and Drug Administration announced today actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with implantable forms of sterilization. The FDA issued a new, mandatory clinical study for Essure to determine heightened risks for particular women. The FDA also intends to require changes to product labeling, including a boxed warning and a Patient Decision Checklist to help to ensure women receive and understand information regarding the benefits and risks of this type of device. The FDA has issued a draft guidance to provide the public an opportunity to comment on the proposed language to be included in these warnings. Since Essure's approval in 2002, the agency has continued to monitor Essure's safety and effectiveness by reviewing the medical literature, clinical trial information, post-approval study data and medical device reports submitted to the agency. The new actions announced today take additional steps and follow the agency's careful evaluation of available information.

"The actions we are taking today will encourage important conversations between women and their doctors to help patients make more informed decisions about whether or not Essure is right for them," said William Maisel, M.D., M.P.H., deputy director for science and chief scientist at the FDA's Center for Devices and Radiological Health. "They also reflect our recognition that more rigorous research is needed to better understand if certain women are at heightened risk of complications."

Essure is a permanent form of birth control that involves the insertion of flexible coils through the cervix and vagina into the fallopian tubes. Over a period of about three months, scar tissue forms around the inserts and creates a barrier that keeps sperm from reaching the eggs, thus preventing conception. While the scar tissue forms, women must use an alternative form of birth control. Over the past 14 years, FDA has reviewed a significant amount of information related to the use of Essure. While the

FDA believes Essure remains an appropriate option for the majority of women seeking a permanent form of birth control, some women may be at risk for serious complications. These may include persistent pain, perforation of the uterus or fallopian tubes from device migration, abnormal bleeding and allergy or hypersensitivity reactions.

The draft guidance issued today by the FDA regarding permanent hysteroscopically-placed sterilization devices aims to increase patient and physician understanding of the potential risks associated with this type of device. The draft guidance provides the public an opportunity to comment on the language that once finalized, will be included in the product labeling to communicate to health care practitioners and patients the potential serious complications that can occur in some women. The Agency intends to require a mandatory box warning on the product explaining the adverse events that have been associated with these devices, including their insertion and/or removal procedures.

The draft guidance also includes proposed language for the "patient decision checklist," for doctors to discuss with patients to better communicate risks and help to ensure an informed decision-making process. The checklist will also help doctors discuss the importance of undergoing a "confirmation" test three months after the device is implanted to determine whether the implants are properly placed and that scar tissue has formed to prevent pregnancy. The checklist should be completed and signed by the patient and physician prior to proceeding with a permanent hysteroscopic sterilization procedure, such as Essure.

The FDA has also ordered Bayer, the company that manufactures Essure, to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment. Bayer will be required to develop and conduct a post-market study that will provide data to help the agency to better understand the risks associated with Essure and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure device. The study will also evaluate how much these complications affect a patient's quality of life. Additionally, it will collect information to identify reasons for why some patients don't have a confirmation test to ensure that Essure has been properly placed three months after insertion. The FDA will use the results of this study to determine what, if any, further actions related to Essure are needed to protect public health.

The FDA is seeking comment from the public, industry, and other stakeholders on this draft guidance. The docket will be open for 60 days.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- Essure Permanent Birth Control (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm)
- Essure: Information for Patients (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452251.htm)
- Draft Guidance: Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization (PDF - 384KB) (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020.pdf)

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